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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,388	02/23/2004	Neil C. Leatherbury	31-31-0027	6576
68622 <b>NORMAN</b> F. H	7590 12/09/200 IAINER. JR.	8	EXAMINER	
SMITH & NEP	HEW, INC.		COMSTOCK, DAVID C	
150 MINUTEMAN ROAD ANDOVER, MA 01801			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	DELIVERY MODE
			12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/785,388	LEATHERBURY ET AL.				
Office Action Summary	Examiner	Art Unit				
	DAVID COMSTOCK	3733				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be timil apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1)⊠ Responsive to communication(s) filed on <u>30 Au</u>	igust 2007.					
	· · · · · · · · · · · · · · · · · · ·					
3) Since this application is in condition for allowan	oplication is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>1-3,5,8 and 24-36</u> is/are pending in the	e application.					
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>24 and 25</u> is/are allowed.						
6)⊠ Claim(s) <u>1-3,5,8 and 26-36</u> is/are rejected.						
7)☐ Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner	-					
10)⊠ The drawing(s) filed on <u>23 February 2004</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Exa		, ,				
Priority under 35 U.S.C. § 119						
<u> </u>	nuicuitu undan 25 H.C.C. \$ 110/a)	(d) on (f)				
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 119(a)	-(a) or (i).				
a) ☐ All b) ☐ Some * c) ☐ None of:	, baye base respined					
1. Certified copies of the priority documents		on No				
2. Certified copies of the priority documents						
3. Copies of the certified copies of the prior		d in this National Stage				
	application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of	or the certified copies not receive	u.				
Attachment(s)	A) [ ]	(DTO 442)				
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) ∐ Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal Pa					
Paper No(s)/Mail Date	6)					

### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 8, 26-27 and 30-36 are rejected under 35 U.S.C. 102(e) as being anticipated by DeMayo (US Patent Publication Number 2003/0065333).

DeMayo discloses a bone or cartilage implant delivery device comprising a tubular outer shaft, e.g. 11, having a proximal and distal end, a longitudinal axis, and an internal bore along the longitudinal axis of the outer shaft, wherein the distal end of the outer shaft is suitable for holding an implant at 3,and an inner shaft, e.g. 12, having a distal end and a proximal end, wherein the proximal end of the inner shaft is suitable for insertion into a defect, wherein the entire inner shaft is adapted to fit within the internal bore of the outer shaft so that the inner shaft and the outer shaft are slidably engaged, wherein one or more of the shafts comprise means to provide friction-retarded movement of the inner shaft through the outer shaft, also comprising an implant disposed within the distal end of the outer shaft, also comprising at least one slot in the distal end of the outer shaft for visualizing the implant, wherein the proximal and distal

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ends of the inner and outer shafts have smooth, rounded surfaces (see figures 1-3).

The distal ends of the shafts include smooth, rounded surfaces, e.g., as along their

outer periphery.

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over DeMayo, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeMayo (US Patent Publication Number 2003/0065333) in view of Spranza et al.(US Patent Number 6,302,887).

DeMayo discloses the claimed invention except the kit containing a knife. Spranza et al. disclose an implant delivery device (see figures 6 and 7) including a knife to cut the surrounding tissue (see column 6, lines 19-20). It would have been obvious to one skilled in the art at the time the invention was made to construct the kit of DeMayo with a knife, in view of Spranza et al. to cut surrounding tissue.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeMayo (US Patent Publication Number 2003/0065333), in view of Smith et al.(US Patent Number 5,697,932), cited by applicant.

DeMayo disclose the claimed invention except the kit containing a plurality of bone delivery devices. Smith et al. disclose a kit and the use of different sized instruments to accommodate surgical needs. It would have been obvious to one skilled in the art at the time the invention was made to construct the kit of DeMayo with a plurality of bone delivery devices, in view of Smith, to accommodate surgical needs.

## Allowable Subject Matter

Claims 24 and 25 are allowed.

## Response to Arguments

Applicant's arguments filed 30 August 2007 have been fully considered but are not persuasive.

The inner shaft, per se, terminates at the longitudinal position where the flange begins. Therefore, the entire inner shaft fits within the through-hole of the outer shaft.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to

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reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733